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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,935	08/08/2001	Stuart D. Edwards	9222.16785-CON	5246

7590

04/18/2003

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 04/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,935

Applicant(s)

EDWARDS, STUART D.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 107-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 107-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Priority

It is noted that in addition to the applications recited in the Cross Reference to Related Applications section of the specification there are numerous other co-pending applications which disclose and claim very similar and/or identical subject matter. In accordance with 37 CFR 1.105 and MPEP 704.11(a) subsection G, applicant is respectfully requested to disclose all co-pending applications and related patents and identify the specific claims of those applications and/or patents which may present double patenting issues with the instant application claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 111-114 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims recite a positive effect of the device on tissue thereby positively reciting the connection of the device to tissue. Human tissue is non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 111-114 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is nothing in the disclosure describing a treatment device which is programmed to treat the sphincter according to the method steps set forth in claim 111. In particular, there is no disclosure of a device programmed to introduce the treatment device into tissue. While that may be the disclosed use of the system, there is no disclosure of a device programmed to perform such a function.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 111-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 111-114 are unclear with the scope of the claim. These claims recite apparent method steps and also appear to be positively reciting human tissue. It is not clear how a device may be programmed to introduce a treatment device into tissue.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 107-114 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-88 of U.S. Patent No. 6,056,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

Claims 107-114 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6,254,598. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

Claims 107-114 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,258,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is

deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

Claims 107-114 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,402,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

Claims 107-114 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-52 of U.S. Patent No. 6,077,257. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

Claims 107-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/776,140. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes

to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 107-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/921,356. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 107-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/943,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 107-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/911,874. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 107-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/971,085. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of mapping electrodes to first detect tissue is deemed an obvious consideration for one of ordinary skill in the art, particularly in view of the Edwards disclosure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

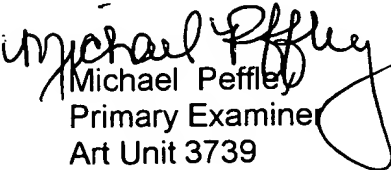
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

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April 16, 2003